UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 21, 2012

MEMORANDUM

SUBJECT: Efficacy Review for EPA Reg. No. 10324-214,
Maguard 5626;
DP Barcode: 399433

FROM: Marcus Rindal, Microbiologist
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TO: Marshall Swindell PM 33
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APPLICANT: Mason Chemical Company
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Formulation from the Label[1]:

Active Ingredient	% by wt.
Peroxyacetic Acid	5.9%
Hydrogen Peroxide	27.3%
Inert Ingredients:	66.8%
Total	100.0%

1 Formulation of test material was confirmed to be identical or substantially similar to the CSF of the "parent product. Testing was conducted at the nominal concentration."

I BACKGROUND

The product, Maguard 5626 (EPA Reg. No. 10324-214), is a registered disinfectant and sanitizer for use on previously cleaned hard non-porous inanimate surfaces in institutional, commercial, and industrial buildings such as dairies, wineries, breweries, food and beverage plants, poultry and egg facilities, and animal housing, hospitals, schools, industrial facilities, office buildings, veterinary clinics. The label states that the product is an effective disinfectant in the presence of 400 ppm hard water and 5% blood serum. The label states that the product is an effective sanitizer when a solution is prepared in water of up to 400 ppm hardness (calculated as $CaCO_3$) according to the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants test. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated July 27, 2011), EPA Form 8570-4 (Basic and Alternative Formulations' Confidential Statements of Formula – dated 11/21/2011), fifty three studies (MRID 485552-09 through 485552-61), Statements of No Data Confidentiality Claims for all fifty three studies, and the proposed label (dated 11/21/2011).

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: appliance exteriors, bathroom fixtures, bed frames, cages, carts, chairs, coolers, counter tops, feeding equipment, floors, furniture, kennel runs, operating tables, racks, shelves, sinks, tables, and walls. In addition, the product is designed for sanitizing pre-cleaned, hard, non-porous surfaces, including: conveyors, drinking utensils, eating utensils, equipment, evaporators, filters, food preparation utensils, pasteurizers, pipelines, saws, slicers, tableware, tanks, and vats. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: glass, glazed porcelain, linoleum, plastic, stainless steel, tile, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product:

> As a disinfectant in non-medical facilities: Prepare a use solution by adding 1.5 ounces of the product and 5 gallons of water (a 1:320 dilution). Apply use solution with a brush, cloth, mop, sponge, or mechanical spray device, coarse pump, or trigger spray device thoroughly wetting surfaces as required. Treated surfaces must remain wet for 10 minutes. Rinse or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.
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> As a disinfectant in institutions: Prepare a use solution by adding 2 ounces of the product and 5 gallons of water (a 1:427 dilution). Apply use solution with a brush, cloth, mop, sponge, or mechanical spray device, coarse pump, or trigger spray device thoroughly wetting surfaces as required. Treated surfaces must remain wet for 10 minutes. Rinse or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.
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> As a sanitizer: Remove gross food particles. Wash with a detergent solution. Rinse with potable water. Prepare a use solution by adding 1-2 ounces of the product and 6 gallons of water (73-146 ppm active; a 1:768-1:384 dilution). Apply use solution to surfaces,

using immersion, coarse spray, or circulation techniques. All surfaces must be exposed for at least 30 seconds. Drain excess solution.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces): Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 × 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria): There are cases where an applicant requests to make claims of effectiveness against additional bacteria for a product that is already registered as a sanitizing rinse for previously cleaned, food contact surfaces. EPA staff indicated that the DIS/TSS-5 standards are silent on this matter and that confirmatory test standards would apply. EPA staff indicated that, for sanitizing rinses for previously cleaned, food contact surfaces, 2 product samples, representing 2 different product lots, must be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control.

Furthermore, according to information in the above AOAC test method itself, counts on number controls for the product should fall between 75 and 125 × 10^6/mL for percent reductions to be considered valid. Label directions for use, however, must state that a contact time of at least 1 minute is required for sanitization.

IV COMMENTS ON THE SUBMITTED STUDY

MRID No. 487177-01, "Germicidal and Detergent Sanitizing Action of Disinfectants" against Salmonella enterica serotype enteritidis (ATCC 4931) by Becky Lien. Study Completion date—September 7, 2010. Project Number—A09962

This study was conducted against *Salmonella enterica* serotype *enteritidis* (ATCC 4931). Two Lots (Lot B and Lot C) of the product, Maguard 5626, were tested according to the

Germicidal and Detergent Sanitizing Action of Disinfectants at a dilution of 1 oz. disinfectant + 767 parts 500 ppm AOAC Synthetic Hard Water and was used within three hours of preparation. An aliquot (99.0 ml) of each lot of test substance at the concentration to be tested was added to duplicate 250-300mL flasks and placed into a 25.0°C waterbath. The test substance was allowed to equilibrate for ≥ 20 minutes. A 1.00 mL of culture suspension was added to each flask as follows (a) the flask was whirled and stopped just before the suspension was added, and (b) the test organism suspension was added midway between the center and edge of the surface with the tip of the pipette slightly immersed in the test solution. The product was tested with a 30 second contact time at 25±1°C with no organic soil load. The neutralizer used was Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase. Post neutralization, four 1.0 mL and 0.1 mL aliquots of the neutralized test solution were transferred into individual sterile Petri dishes. The subculture medium was Tryptone Glucose Extract Agar. All subculture plates were incubated for 46 hours at 35-37°C. The plates were visually examined for the growth. Upon receipt to the testing facility, the active ingredient concentration was measured at the nominal level.

V RESULTS

Neutralization Confirmation Control Results							
Test Substance Maguard 5%-PAA	Test Organism	Date Performed	Dilution	Numbers Control Inoculum (1.0 mL) CFU	Volume of Neutralized Inoculated Product CFU	Log Difference 1.0 mL Data	Pass/Fail ±1.0 Log_{10}
Lot B	*Salmonella enterica**	8/12/10	10^{-9}	13, 9	11, 15	-0.07	Pass
Lot C					7, 12	0.04	Pass

* Serotype *enteritidis* (ATCC 4931)

Raw Data for *Salmonella enterica* serotype *enteritidis* (ATCC 4931)						
Test Substance Maguard 5%-PAA	Exposure Time	Run Number	Duplicate Plate Counts (CFU/plate) 2 sets of 4 plates for each volume			
			Number Surviving		Microbes Initially Present	
			Test 0.1 mL of 10^{-1} (in neutralizer)	Test 1.0 mL of 10^{-1} (in neutralizer)	Numbers Control 0.1 mL of 10^{-6}	Numbers Control 1.0 mL of 10^{-6}
Lot B	30 seconds	Run 1	0, 0, 0, 0	0, 0, 0, 0	11, 10, 8 10	89, 116, 103, 124
		Run 2	0, 0, 0, 0	0, 0, 0, 0		
Lot C		Run 1	0, 0, 0, 0	0, 0, 0, 0		
		Run 2	0, 0, 0, 0	0, 0, 0, 0		

Calculated Results for *S. enterica* by Lot, Exposure, and Corresponding % Reduction				
Test Substance Maguard 5%-PAA	Exposure Time	Average Number Surviving (CFU/mL)	Microbes Initially Present Numbers Control (CFU/mL)	Percent Reduction
Lot B	30 seconds	$<1\times10^{1}$	1.08×10^{8}	>99.999%
Lot C		$<1\times10^{1}$		>99.999%

Maguard 5%-PAA (Lot B and Lot C), diluted at 1 oz. per 6 gallons defined as 1 part test substance + 767 parts of 500 ppm AOAC Synthetic Hard Water, demonstrated a >99.999 percent reduction of *Salmonella enterica* serotype *enteritidis* (ATCC 4931), after a 30 second exposure time at 25.0°C.

VI CONCLUSIONS

Under the conditions of the submitted study (MRID No. 487177-01), Maguard 5%-PAA (Lot B and Lot C) diluted at 1 oz. per 6 gallons defined as 1 part test substance + 767 parts of 500 ppm AOAC Synthetic Hard Water, demonstrated efficacy against *Salmonella enterica* serotype *enteritidis* for pre-cleaned, nonporous food contact surfaces after a 30 second exposure time.

VII RECOMMENDATIONS

1. Based on the submitted study, the proposed label is acceptable regarding the use of the product, Maguard 5%-PAA (Lot B and Lot C) diluted at 1 oz. per 3 gallons of 400 ppm AOAC Synthetic Hard Water against *Salmonella enterica* serotype *enteritidis* for pre-cleaned, nonporous food contact surfaces for a 60-second contact time. The registrant must confirm that the tested product, Maguard 5%-PAA is identical to Maguard 5626, the subject of the current efficacy review.

2. The proposed label claim is unacceptable regarding the use of the product, Maguard 5%-PAA (Lot B and Lot C) diluted at 1 oz. per 6 gallons of 400 ppm AOAC Synthetic Hard Water against *Salmonella enterica* serotype *enteritidis* for pre-cleaned, nonporous food contact surfaces for a 30-second contact time. According to DIS/TSS-4, the label must reflect a contact time of 1 minute.

3. On page 1 of the proposed label, clarify the "bacteria" as "odor-causing bacteria" for recirculating cooling water, evaporative coolers, reverser osmosis, filtration and agricultural waters.

4. The Data Matrix incorrectly identifies the recently submitted test as AOAC Use Dilution for *Salmonella enterica* serotype *enteritidis* when the method conducted is the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants test.